



WinKQCL™ 5 Endotoxin Detection Software – Using Trending and Other Advanced Features

David Herbst / 25 March 2014

Saskia Ihle / 26 March 2014

Lonza Walkersville, Inc., Walkersville, MD 21793 / March 2014

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60-Minute Agenda

- Part 1: Money-saving and Time-saving features
- Part 2: New security features that ensure compliance to 21 CFR Part 11 and internal security policies
- Part 3: How to effectively use the trending feature to support OOS/OOT investigations
- Questions and Answers

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Part 1: Money and Time-Saving Ideas

- “The most expensive tests are the retests”
- Use WinKQCL™ Software to work smarter
- Reduce deviations and retests
- Features that save time and money:
 - Prevent retests where you have split pair/split replicate events
 - How to keep spot contamination from invalidating your standard curve
 - Barcode scanning and other data automation features to reduce manual entry errors

Split Replicate Detection

■ Problem:

- A split pair or a split replicate is a case where one replicate reacts and one does not, resulting in a reaction time for one replicate and not the other
- For duplicates this will result in an undefined %CV
- Most companies will retest

■ Solution:

- Lonza's Kinetic SmartStop™ Feature
- Demo video next slide

Spot Contamination

■ Problem:

- When individual blanks, standards, or product replicates become contaminated, they cause a %CV failure or cause the blank and low standard to overlap.
- In the case of invalid standard curves, the entire plate must be retested.
- In the case of an invalid sample, the sample and PPC must be retested.

■ Solution:

- WinKQCL™ version 5 Software allows one to setup extra negative controls, standards, increase replicates, and/or mask hot wells

Spot Contamination – Template Options

Template Manager -

	1	2	3	4	5	6	7	8	9	10	11	12
A	BLNK	BLNK	S1 Vacc LOT121	S1 Vacc LOT121	S9 WFI Loop 1	S9 WFI Loop 1	S17 WF Loop 2	S17 WF Loop 2	S25 WF Loop 2	S25 WF Loop 2		
B	BLNK	BLNK	S2+ Var LOT121	S2+ Var LOT121	S10+ W Loop 1	S10+ W Loop 1	S18+ W Loop 2	S18+ W Loop 2	S26+ W Loop 2	S26+ W Loop 2		
C	STD1 0.0100	STD1 0.0100	S3 Vacc LOT121	S3 Vacc LOT121	S11 WF Loop 1	S11 WF Loop 1	S19 WF Loop 2	S19 WF Loop 2				
D	STD1 0.0100	STD1 0.0100	S4+ Var LOT121	S4+ Var LOT121	S12+ W Loop 1	S12+ W Loop 1	S20+ W Loop 2	S20+ W Loop 2				
E	STD2 0.100	STD2 0.100	S5 Vacc LOT121	S5 Vacc LOT121	S13 WF Loop 1	S13 WF Loop 1	S21 WF Loop 2	S21 WF Loop 2				
F	STD3 1.00	STD3 1.00	S6+ Var LOT121	S6+ Var LOT121	S14+ W Loop 1	S14+ W Loop 1	S22+ W Loop 2	S22+ W Loop 2				
G	STD4 10.0	STD4 10.0	S7 Devi LOT125	S7 Devi LOT125	S15 WF Loop 2	S15 WF Loop 2	S23 WF Loop 2	S23 WF Loop 2				
H	STD5 100	STD5 100	S8+ De LOT125	S8+ De LOT125	S16+ W Loop 2	S16+ W Loop 2	S24+ W Loop 2	S24+ W Loop 2				

Setup Standards Lot / Exp Accessories Parameters

BLNK	0	Number of standards	5
BLNK	0	Units	EU
STD1	0.0100	<input checked="" type="checkbox"/> Enable separate Standards layout	
STD2	0.100	Replicates	2
STD3	1.00	Replicate Direction	Horizontal
STD4	10.0	Sample Fill Direction	Vertical
STD5	100		

Preset Curve

My Standard Curve

Save Delete

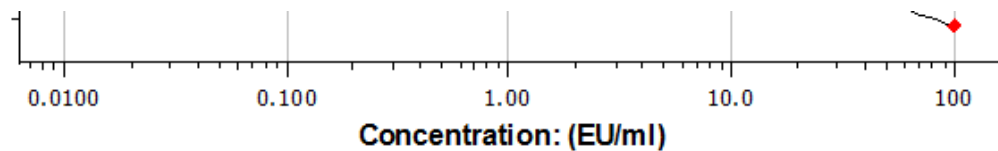
Stored Curve

Stored curve query not performed.

Search

Use

Spot Contamination – Data Analysis



<u>Standards Results</u>					
Standards	Conc./Dil.	Well	Reaction Time (sec)	Average Reaction Time (sec)	Back Prediction (Power Curve)
Blank	Blank	A 1	4440	4498	< 0.0100
		A 2	4555		
		A 3	4130 !!		
Std. 1	0.01	B 1	2340	2325	0.00998
		B 2	2395		
		B 3	2240		
Std. 2	0.1	C 1	1140	1144	0.100
		C 2	1145		

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Barcode Scanning/Data Import

■ Problem:

- Labels are difficult to read
- Manual data entry is error prone

■ Solutions:


- Scan in data via a handheld barcode scanner (Lonza P/N: 25-507)
- New data import feature
- Lonza's PyroTec™ Solution allows automatic import of sample barcodes

Barcode Scanning

- Starting with version 4.0.3, the WinKQCL™ Software supports scanning reagent data directly into the template using the 2D barcode printed on our vials



**Limulus Amebocyte Lysate
Kinetic-QCL™ Reagent, 2.6 ml**
 Part No.: K50-643 US License # 1775
Lot No.: NL086EHWVC Exp. Date: 17 APR 2016
 Store at 2 ° to 8 °C
 See package insert for warnings and instructions.
 For Endotoxin Detection Use
 (rev. 3/12)



Lonza
Walkersville, MD USA
301-898-7025, www.lonza.com

08509

	Lot Number	Expiration
LAL	NL086EHWVC	<input checked="" type="checkbox"/> 04/17/2016
Water	0000375934	<input checked="" type="checkbox"/> 05/31/2017
Endotoxin	0000373753	<input checked="" type="checkbox"/> 02/29/2016

Barcode Scanning

- WinKQCL™ Software supports quickly filling product lists with lot numbers and/or tracking IDs using our SpeedFill™ Feature



H S2+ V S2+ V S10+ S10+ '
 00489 00489 00490 00490

Products

	Num. Smpls	Name	Lot No.	ID	Rel. Lim.	ET per	Dil./Conc
Copy	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
1	1	WFI	004897		≤ 0.250	ml	▼ 1
1	1	WFI	004898		≤ 0.250	ml	▼ 1
1	1	WFI	004899		≤ 0.250	ml	▼ 1
1	1	WFI	004900		≤ 0.250	ml	▼ 1
1	1	WFI	004901		≤ 0.250	ml	▼ 1
*	1	WFI			≤ 0.250	ml	1

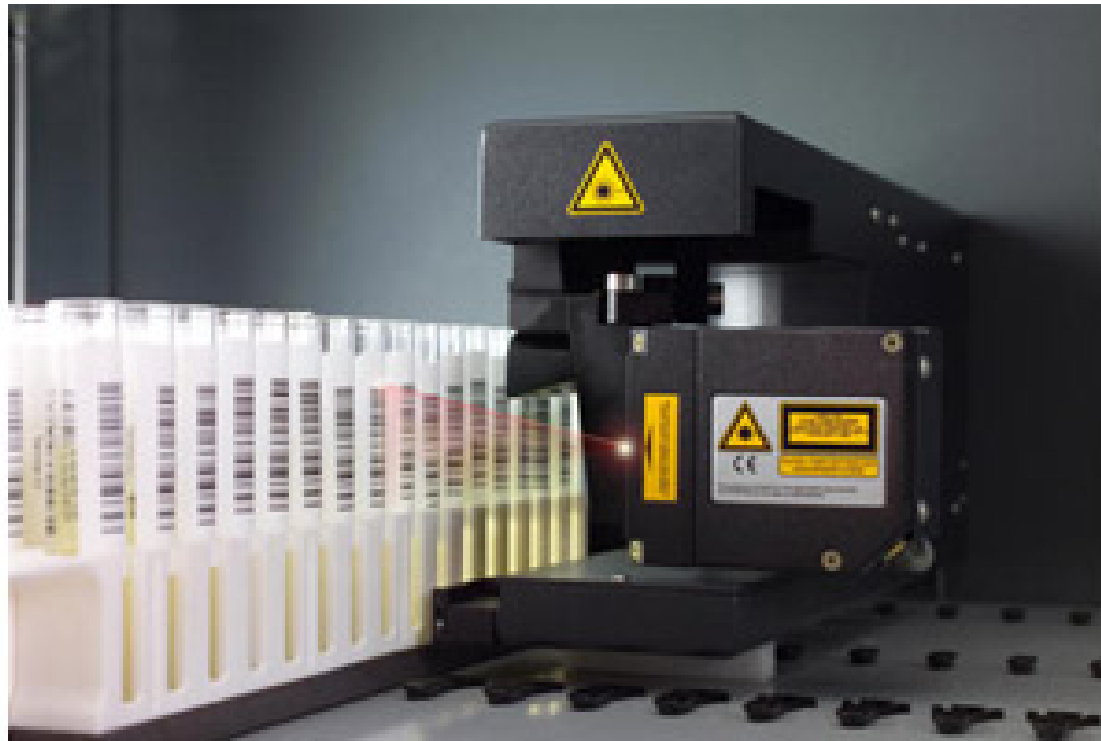
SpeedFill

Data Import

- WinKQCL™ Software now supports bi-directional interfaces with 3rd party sample tracking systems
- These 3rd party systems include Lonza's MODA™ Environmental Monitoring system, commercially available LIMS, LIS and custom-made sample tracking systems
- WinKQCL™ Software will automatically import sample testing worklists and display this information in the template manager.

PyroTec™ Robot Barcode Scanning

- WinKQCL™ Software is also fully integrated with Tecan's EVOware® Software
- Lonza's PyroTec™ Solution can be integrated to automatically import barcode information from the sample tubes using the built-in scanner



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Part 2: New Security Features

■ Problem:

- Software must comply with regulatory, industry, and company security requirements
- Software must still be flexible and easy to use

■ Solutions:

- WinKQCL™ 5 Software introduces many new security enhancements which improve both compliance and ease-of-use

New Security Features

- WinKQCL™ Software continues to meet the technical requirements for 21 CFR Part 11 and support the European Annex 11 guidance
- New features enable flexibility and easier adherence
- WinKQCL™ 5 Software and higher now support:
 - IT initiatives to secure all data under one central database and segregate data into laboratory workgroups
 - Restriction of user access to individual laboratory workgroup data
 - The use of your Windows® password
 - Activity timer settings to allow WinKQCL™ Software to match company policies
 - Flexible, user-specific access rights configuration

New Security Features – Data Security

■ Data Storage:

- Endotoxin data is GMP data!
- Do not store it on your laboratory computer!
- If you are storing your data on a laboratory computer and not backing it up daily, have your IT department contact scientific support, we can assist in securing your data

New Security Features – Data Security

- Lonza has supported a true client-server network since 2004
- Starting with WinKQCL™ 5 Software, data can be centralized and shared across sites, even if these sites are in different countries
- Steps to securing your data:
 - Work with IT to identify an existing database server that can be used
 - WinKQCL™ Software has tools that can import and merge existing data
 - Install the client software on all lab and office computers



New Security Features – Passwords

- Never forget your password again! Starting with WinKQCL™ 5 Software, you can use the same password you use to log in to Windows®

The screenshot shows a Windows-style dialog box titled "Editing User: ANALYST". It has several tabs: "User Details", "Permissions", "Password", "Status", and "Workgroup". The "User Details" tab is active. At the top, there is a text box with the instruction: "Please enter the user's signature, which will appear at the bottom of reports." Below this are four text input fields: "User ID:" (containing "BJONES" and marked with a red "1"), "Name:" (containing "Bob Jones"), "Signature Text:" (containing "Bob W. Jones"), and "Scanned Signature:" (empty). Below the "Scanned Signature" field are two buttons: "Load Signature" and "Clear". At the bottom left, there is a checked checkbox labeled "2" with the text "Uses Active Directory Authentication". Below this is a "Domain Name:" field (containing "DOMAIN") and a "Check Name" button (marked with a red "3"). At the very bottom of the dialog are three buttons: "Save", "Print", and "Cancel".

New Security Features – Password Rules

- Set the WinKQCL™ Software password rules to match company policy:
 - Set the inactivity timer
 - Enable/disable active directory “single sign-on” (SSO) feature. SSO allows WinKQCL™ Software to automatically log you in with the password you used to log in to Windows®.
 - **When applying e-signatures and cancelling tests, the WinKQCL™ Software will always require passwords**

New Security Features – User Access

- WinKQCL™ 5 Software adds user access flexibility:
 - Per 21 CFR Part 11, assign access according to the user's training/role in the company
 - Use these features to restrict access of non-QC or less experienced QC personnel or increase it for experienced personnel/managers
 - Allow/restrict access to specific workgroups

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Part 3: How to Effectively Use Trending

- Problem:
 - Customers need an easy way to review and monitor data
- Solutions:
 - WinKQCL™ 4 Software and higher introduce a new generation of integrated trending and data analysis capability
 - WinKQCL™ 5 Software adds additional standards data analysis capability
 - How to use trending...

How to Effectively Use Trending

- First, and most importantly, users in the lab must get into the habit of inputting all data consistently and accurately
- Examples of inconsistent data:
 - Water ≠ WFI ≠ Water for Injection
 - P20 Pipette ≠ 20ul Pipette
- Examples of poorly entered data:
 - “0.9% Sodium Chloride Injection 26MAR2014”
 - “Eppendorf® 20ul Pipetter”
 - Data elements need to be separated into appropriate fields

Maintaining Products Lists

- Break each piece of information about the test article into separate fields

The screenshot shows a dialog box titled "Edit Product" with the following fields and values:

- Product Name: Water For Injection
- Lot Number: Loop 1
- Product Id: Drop ID 01
- Endotoxin Concentration per: ml
- Sample Count: (empty)
- Release Limit: ≤ 0.250
- PPC: Yes 0.5
- Allow multiple dilutions
- Dilution: 1
- Comment: (empty)
- Workgroup: QC Micro Lab

At the bottom of the dialog are four buttons: Calculator, Help, OK, and Cancel. Red arrows point to the Product Name, Lot Number, Product Id, and Comment fields.

Maintaining Your Accessories

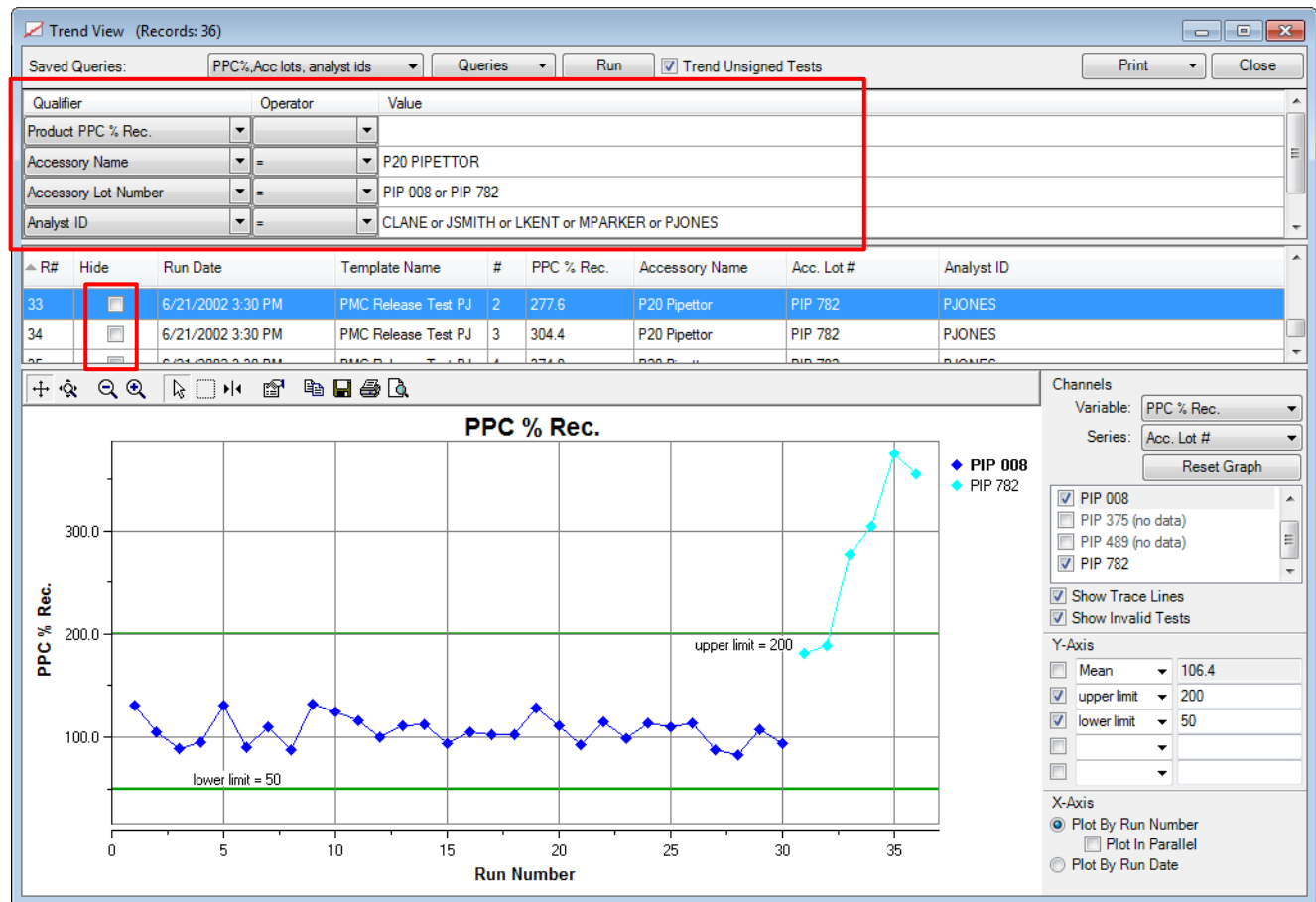
- Just like with products, it is important to associate an accurate and consistent list of accessories used with each test to allow for effective trending and investigations
- WinKQCL™ Software allows maintenance of a global list of accessories used for each laboratory
- Each user can create their own default list from this global list to save time when setting up their template
- It is possible to assign a calibration technician or a specific analyst with the responsibility of maintaining this list, while locking out all other users

Using Trending

- Once you have started collecting data consistently, it is just a matter of determining what you want to see and selecting the matching qualifiers
- WinKQCL™ Software allows selection of any data associated with the test, including the following:
 - General endotoxin test data, including the date range, analysts, reader serial numbers, workgroups, reagent lot numbers, and more.
 - All Product and Accessory data
 - Standard curve parameter data and raw data

Using Trending

- User can query based on any number of Qualifiers
- One window shows query, results table, and graph.
- Ability to mask outliers



Using Trending

- Examples of questions you may wish to answer using the trending feature:
 - Does my water loop show an increase in endotoxin over time?
 - Does any specific drop show positive results more often than another, and if so, at what frequency?
 - Is the % PPC Recovery on my product consistent from lot to lot? Do I see a trend that should be investigated, before a failure occurs?
 - I am using a new accessory, reader, or analyst in my lab, let me compare performance of one vs. another using quality indicators, such as %CV, R-Value, or blank/low standard separation

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Do You Have More Questions?

- Contact our Scientific Support
scientific.support.eu@lonza.com
scientific.support@lonza.com
- Join our upcoming webinar on 3 and 4 June:
Endotoxin Testing and Regulatory Requirements
- Register at:
<http://www.lonza.com/qcwebinars>